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*Pro Hac Vice Application To Be Submitted

MONTANA FIRST JUDICIAL DISTRICT COURT
LEWIS AND CLARK COUNTY

STATE OF MONTANA, Plaintiff, v. PURDUE PHARMA L.P., PURDUE PHARMA, INC., THE PURDUE FREDERICK COMPANY INC., and RHODES PHARMACEUTICALS L.P., and JANE DOES 1-10, Defendants.	)	Cause No. ~~ADV-2017-949~~ CV-18-33-H-SEH **COMPLAINT** MIKE MENAHAN PRESIDING JUDGE

63544

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I. PRELIMINARY STATEMENT

1. There is an opioid crisis in Montana. "Prescription drug abuse and diversion is a growing epidemic—it affects everyone, and the statistics are staggering."[1] The epidemic began not with an outbreak, but with a business plan. It is the result of a corporate decision by Purdue Pharma L.P., and the related corporate entities named as Defendants in this lawsuit (collectively, "Purdue"), to promote opioids deceptively and illegally in order to significantly increase sales and generate billions of dollars in revenue for Purdue's private owners, the Sackler family. As laid out below, Purdue's misrepresentations regarding the risks and benefits of opioids enabled, and is continuing to enable, the widespread prescribing of opioids for common, chronic pain conditions like low back pain, arthritis, and headaches.[2] As a direct consequence, the rampant use, overuse, and abuse of opioids is devastating Montana and its families.

2. Purdue is not a typical pharmaceutical company. It sells powerful narcotics called opioids, and it has virtually no other product line.[3] Purdue is also—by far—the largest opioid marketer in Montana.

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[1] Montana Medical Association, *Know Your Dose*, http://knowyourdosemt.org (last visited Nov. 30, 2017).

[2] Consistent with the commonly accepted medical usage, the term "chronic pain" as used herein refers to non-cancer pain lasting three months or longer.

[3] Since 1970, opioids have been regulated under the Controlled Substances Act ("CSA"). Controlled substances are categorized in five schedules, ranked in order of their potential for abuse, with Schedule I the highest. The CSA imposes a hierarchy of restrictions on prescribing and dispensing drugs based on their medicinal value, likelihood of addiction or abuse, and safety. Opioids generally have been categorized as Schedule II or Schedule III drugs. Schedule II drugs have a high potential for abuse, have a currently accepted medical use, and may lead to severe psychological or physical dependence; Schedule III drugs are deemed to have a lower potential for abuse, but their abuse may lead to moderate or low physical dependence or high psychological dependence. 21 U.S.C. § 812. OxyContin and Hysingla ER are Schedule II drugs; Butrans is a Schedule III drug.

While described as a class, opioids also have different active pharmaceutical ingredients ("API"). The API in Purdue's OxyContin is oxycodone, Hysingla is hydrocodone, and Butrans is buprenorphine. There also are extended release or long-acting opioids and immediate release or short-acting opioids. OxyContin, Butrans, and Hysingla are all extended-release opioids.

3. Likewise, opioids are not typical pharmaceutical products. They are highly addictive synthetic drugs derived from opium—pharmacologically similar to heroin. The U.S. Drug Enforcement Administration ("DEA") has categorized opioids as having a "high potential for abuse[.]" The Centers for Disease Control and Prevention ("CDC") declared that "[o]pioid pain medication use presents serious risks, including overdose and opioid use disorder" (a diagnostic term for addiction).[4] As the Director of the CDC has noted: "We know of no other medication routinely used for a nonfatal condition that kills patients so frequently."[5]

4. Before Purdue's marketing campaign, doctors wrote few prescriptions for opioids, reserving their use mostly for acute cancer pain, post-surgery recovery pain, and end-of-life care. That is because doctors feared that opioids were too addictive to be used long-term and too dangerous to use for relatively minor chronic pain conditions. In an aggressive marketing campaign, which harnessed respected doctors and seemingly neutral patient advocacy groups and professional associations, Purdue falsely claimed that opioids could be prescribed by doctors and used as a first-line, long-term treatment for patients with chronic pain without a material risk of addiction. Other deceptive messages spread by Purdue included the concocted concept of "pseudoaddiction," which a Purdue key opinion leader invented to make doctors wrongly believe that patients who exhibit addictive behaviors are instead exhibiting signs of undertreated pains and should be treated with more opioids—the medical equivalent of fighting fire with gasoline. Purdue also misrepresented the risks, benefits, and superiority of using opioids to treat chronic pain, and claimed that its abuse-deterrent opioids were not only safer than alternatives, but prevent abuse, diversion, and injury—claims not only unsupported by, but contrary to, the

[4] CDC Guideline for Prescribing Opioids for Chronic Pain ("CDC Guideline") at 2.

[5] Thomas R. Frieden and Debra Houry, New England Journal of Medicine, "Reducing the Risks of Relief—The CDC Opioid-Prescribing Guideline" at 1503 (Apr. 21, 2016).

evidence available to Purdue. Purdue's promotional claims were dangerously, and too often fatally, false.

5. In truth, roughly one in four patients who receive prescription opioids long-term for chronic pain in primary care settings will become addicted. According to the CDC, one out of every 550 patients started on opioid therapy dies of opioid-related causes a median of 2.6 years after their first opioid prescription. Moreover, several studies show that long-term opioid use may actually worsen pain and function. This is in addition to the symptoms of withdrawal that long-term users often face.

6. The results of Purdue's marketing campaign have been extremely good for Purdue and the Sackler family, but disastrous for America. With less than 5% of the world's population, the United States now consumes about 80% of the world's opioid supply. [redacted]

7. At the same time, opioids have created a national and a statewide emergency. According to the CDC, 145 Americans now die every day from opioid overdoses. In Montana, since 2000, there have been more than 700 deaths from opioid overdoses. In 2011-2013 alone, prescription drug overdoses were responsible for at least 369 deaths in the state and more than 7,200 hospital inpatient admissions and emergency department visits; and opioids are the most common substance associated with drug poisoning deaths in Montana. Prescription drug abuse in the state is 15 times more deadly than methamphetamines, heroin and cocaine combined.

8. The road, for most opioid victims, began with a prescription. They went to their doctor for a back injury, arthritis or other such painful condition and were prescribed and took opioids, trusting that they were safe. Others began with opioids found in medicine cabinets, the direct result of an oversupply of opioids; this diversion from legitimate uses is a special problem in rural states, including Montana.

9. The human toll of the opioid epidemic is too easily lost in the statistical tally, but they tell the story of the opioid epidemic in Montana.

10. Gail Robin Sharp was named the first Ms. Blackfeet. She worked as a certified nursing assistant on the Blackfeet Reservation in Browning. She started taking prescription drugs after an injury and became addicted. Ultimately, she was found on the street, brain-dead. "I had to take her off life support because she was never going to come back." "I mean, to me, if a doctor gives it to you, you know, it should be okay, right?" Instead, "addiction happened to her." "Prescription drug abuse took a lot of [my mother's] dignity." Willie Ramirez, Livingston.[6]

11. "[A]n injury that required my daughter to have surgery catapulted her into massive prescription and non-prescription drug use: OxyContin, Fentanyl patches, methamphetamines, alcohol, cocaine, marijuana, etc. She was getting them anywhere she could. Stealing them, buying them on the street, over the internet, and doctor shopping." Mother in the Flathead. [7]

12. "My mom is also a prescription drug addict. She and my husband have used together for the past two years. The only difference between the two of them is that my mom is

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[6] Resolve Montana, Montana Attorney General's Office of Consumer Protection, www.https://resolvemontana.org/ (last visited Nov. 8, 2017).

[7] *Id.*

prescribed her pills and my husband is not." "When I was growing up she was an amazing mother. She never used any type of drugs and worked three jobs to support my brother and me. It wasn't until she was diagnosed with these problems that I saw her downfall." Great Falls.[8]

13. The State of Montana and its citizens have borne the costs of Purdue's deceptive marketing. Many of these injuries—in lives ended or lost to addiction—can neither be calculated nor ever adequately compensated. Through this civil enforcement action, the State seeks: (a) injunctive relief to stop Purdue's deceptive marketing; (b) damages for, and abatement of, the public health epidemic that Purdue has created; (c) three times the amount of damages sustained by the State in paying for opioids for first-line treatment of chronic pain and treating the adverse effects of opioid use through the Montana Medicaid Program and the Montana Healthcare Plan; (d) damages, including punitive damages, for money spent by the State as a result of Purdue's conduct; (e) disgorgement of Purdue's unjust profit; and (e) the maximum civil penalties allowed for each violation of the law, along with any other injunctive and equitable relief within this Court's powers to redress and halt Purdue's unlawful practices.

II. PARTIES

14. The Plaintiff State of Montana brings this action, by and through its Attorney General, Tim Fox, in its sovereign capacity in order to protect the interests of the State and its citizens as *parens patriae*. The Attorney General brings this action pursuant to his constitutional, statutory, and common law authority, including the authority granted to him by Mont. Code Ann. §§ 2-15-501 and 502; the Montana Unfair Trade Practices and Consumer Protection Act, Mont.

[8] *Id.*

Code Ann. §§ 30-14-101 through 30-14-144; and the Montana False Claims Act, Mont. Code Ann. §§ 17-8-401 through 17-8-416.

15. Purdue Pharma, L.P. is a limited partnership organized under the laws of Delaware with its principal place of business in Stamford, Connecticut. Purdue Pharma, Inc. is a New York corporation with its principal place of business in Stamford, Connecticut. The Purdue Frederick Company Inc. is a New York corporation with its principal place of business in Stamford, Connecticut. Rhodes Pharmaceuticals, L.P. is a limited partnership organized under the laws of Delaware with its principal place of business in Coventry, Rhode Island. These parties are collectively referred to as "Purdue."

16. Through each of these entities, Purdue manufactures, markets, and sells prescription opioid pain medications, including the brand name drugs OxyContin, Butrans, and Hysingla ER, as well as generic opioids. Purdue has been a leading force in the prescription opioid market, both nationwide and in Montana. [redacted]

17. Jane Does 1-10 are Purdue officers, directors, executives, or agents who were directly and personally involved in developing and executing its marketing efforts, whose names the State does not now know and cannot now ascertain. The State, therefore, sues said Defendants by such fictitious names and will ask leave to amend this Complaint to show their true name(s) when ascertained.

III. JURISDICTION AND VENUE

18. Jurisdiction over the subject matter of this cause of action is proper based upon Mont. Code Ann. § 3-5-302.

19. This Court has personal jurisdiction over Purdue because Purdue does business in Montana and/or has the requisite minimum contacts with Montana necessary to constitutionally permit the Court to exercise jurisdiction, with such jurisdiction also being proper under Montana's long arm rule. Mont. R. Civ. P. 4. Among other business activities in Montana, Purdue employs a substantial number of people in Montana to visit Montana doctors in their Montana offices for the purpose of delivering marketing messages and encouraging such doctors to write prescriptions for Purdue's products.

20. Venue is appropriate in this Court pursuant to Mont. Code Ann. § 30-14-111(3).

21. Because the State of Montana is not a citizen for purposes of diversity jurisdiction, no federal court can exercise subject matter jurisdiction over this case by virtue of diversity of citizenship. The Attorney General does not represent or seek relief on behalf of consumers, either individually or as a class, but acts pursuant to his constitutional, common law, and statutory authority to protect the interests of the State.

22. The Attorney General has constitutional, common law and statutory authority to pursue legal actions in the public interest and has determined that this action on behalf of the State of Montana is in the public interest, including for purposes of Montana Code section 30-14-111.

IV. PURDUE CREATED THE MARKET FOR CHRONIC USE OF OPIOIDS THROUGH DECEIT.

23. Purdue's pain franchise is built on deception. Before Purdue launched OxyContin in 1996, opioids were widely recognized as highly addictive, and therefore only suitable for

severe pain and short-term use, except for when a patient was dying. There was no evidence that opioids were appropriate or could be used safely long-term for most patients.

24. But the market for acute and end-of-life pain was relatively small. Thus, when Purdue launched OxyContin, it sought to broaden its use to chronic pain—back pain, arthritis, and headaches, for example—which not only is more widespread, but entails months or even years of treatment–and, thus, sustained revenue. Purdue, however, found that doctors were too worried about the risk of addicting their patients to prescribe its opioids for regular aches and pains.

25. [redacted]

26. [redacted]

27. [redacted]

28. Not only did Purdue fail to correct this obvious misperception of OxyContin's strength, but it also misrepresented its risks. Purdue set out to—and did—convince doctors that, while opioids were generally addictive, patients with legitimate pain under a doctor's care would not become addicted. For example, [redacted]

29. In addition to its branded promotion, Purdue also used general, unbranded materials, produced by Purdue or by seemingly independent third parties, to build the market for chronic opioids. (Unbranded promotion does not name a specific drug and is often more

persuasive because it does not seem to be product advertising.) [redacted] [redacted] "Pain as a Fifth Vital Sign," an initiative of the Joint Commission for the Accreditation of Hospital Organizations ("JCAHO"), and ensured that virtually every health care facility and provider in the country, including those in Montana, learned its recommendation that pain should be assessed along with a patient's pulse and blood pressure. Once doctors asked about pain, they were obligated to treat it, and Purdue made sure that doctors knew that opioids were an appropriate option.

30. The long-term use of opioids for chronic pain is particularly dangerous because patients develop tolerance to the drugs over time, requiring higher doses to achieve their effect. At high doses, opioids depress the respiratory system, eventually causing the user to stop breathing, which is what makes opioid overdoses fatal. Patients also quickly become dependent on opioids and will often experience physically and psychologically agonizing withdrawal symptoms, which may last for weeks, making it very hard for patients to discontinue their use after even relatively short periods of time. The risk of addiction increases with the duration of use, and causes patients to use opioids at ever-higher doses, even when they are causing harm. It is this mix of tolerance, dependence, and addiction that has made the use of opioids for chronic pain so lethal.

31. Purdue attributed the problem of opioid abuse and overdose to patients who were seeking the opioids, not the drugs themselves. A public statement by Purdue executive Michael Friedman was typical of Purdue's tilt: "Virtually all of these reports [of opioid abuse] involve people who are abusing the medication, not patients with legitimate medical needs."[9] Yet, contrary to Purdue's misrepresentations, pain patients who use opioids precisely as prescribed by

[9] Patrick Radden Keefe, "The Family That Built an Empire of Pain," *The New Yorker* (Oct. 30, 2017), https://www.newyorker.com/magazine/2017/10/30/the-family-that-built-an-empire-of-pain.

a legitimate doctor can—and do—become addicted. Addiction is the result of using opioids, not just misusing or abusing them.

32. Furthermore, Purdue has claimed in other contexts that its responsibility for the opioid epidemic is relieved by the independent actions of doctors who make their own decisions about whether to prescribe opioids and which drugs to use. However, Purdue's marketing deliberately set out to change prescribers' attitudes about opioids. Therefore, the company can hardly claim to be either surprised by or blameless for those results. Purdue knows from its own tracking that its promotion influences prescribers' decisions, [redacted]. That explains why Purdue invests heavily in ensuring that its sales representatives visit doctors frequently—it works.

33. In 2007, Purdue entered into a plea agreement and settlements with federal and state governments, including Montana, to resolve potential civil and criminal enforcement actions. Purdue pleaded guilty to the federal felony of misbranding of a drug with intent to defraud or mislead, admitting that it had lied to doctors about OxyContin's abuse potential, and paid $600 million in fines. Purdue also entered into a Consent Judgment with the State of Montana, agreeing, as in other states, to cease its fraudulent marketing, to no longer misrepresent the risk of addiction to OxyContin, to provide "fair balance" in conveying the risks and benefits of OxyContin, and to implement an abuse and diversion detection system to identify and address suspicious prescribing.

V. PURDUE CONTINUED TO AGGRESSIVELY AND DECEPTIVELY MARKET ITS OPIOIDS FOR CHRONIC PAIN.

34. The 2007 settlements did not mark a change in Purdue's culture or conduct. Because what Purdue was told by doctors in the mid-1990s remains true—that doctors will not

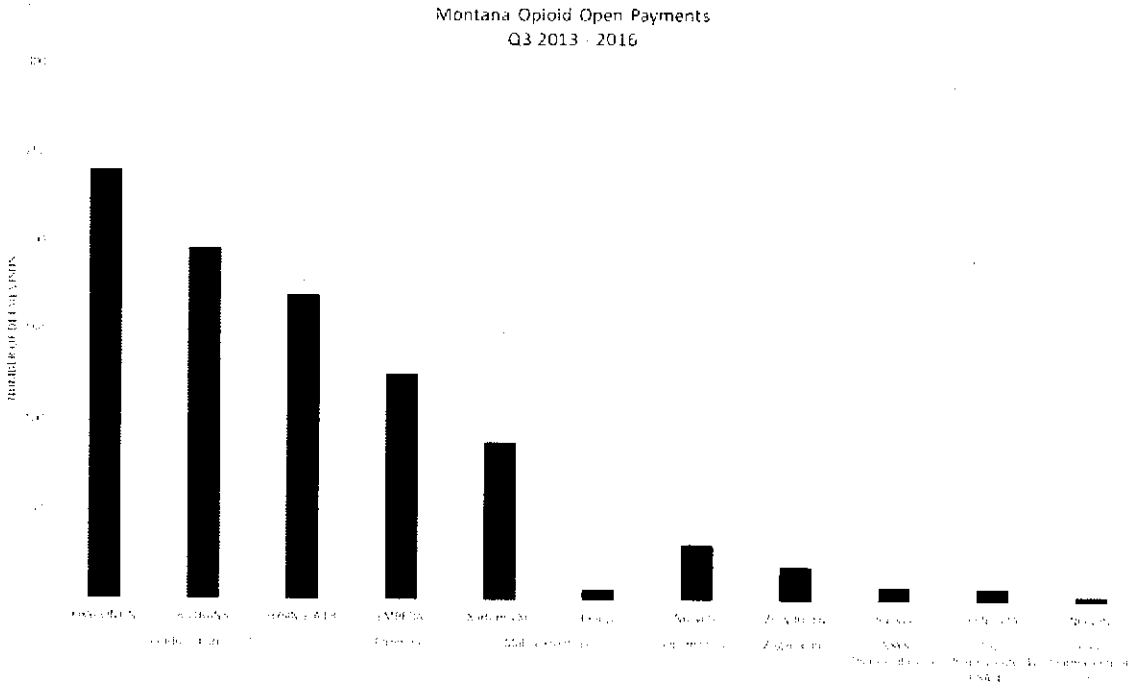
prescribe a highly addictive drug long-term for relatively modest pain—Purdue's multi-billion dollar franchise depends upon continuing to mislead doctors and consumers. Purdue developed and deployed a comprehensive, sophisticated strategy to do so.

[redacted]

35. [redacted]

36. [redacted]

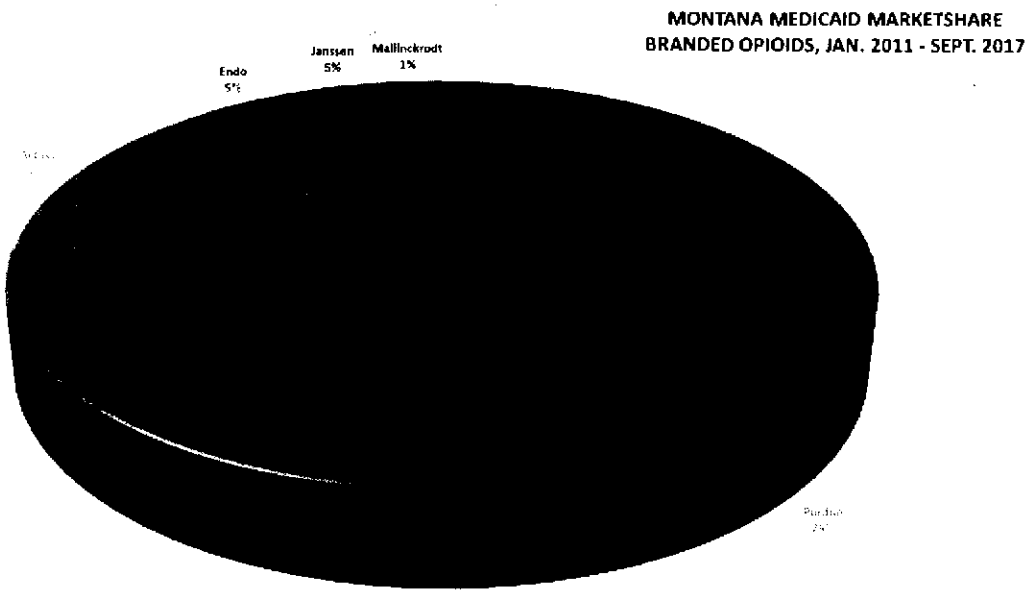
39. Purdue's sales visits in Montana far exceeded those of any other opioid maker.



40. Purdue knew that a small set of doctors were responsible for the vast majority of its sales in Montana, and their prescribing patterns should have sounded alarms. During the past six years, about 800 doctors wrote Purdue opioid prescriptions that were submitted to the Montana Medicaid Program, yet just 31 of these prescribers accounted for about half of such spending. [redacted] Instead of reporting potentially suspicious prescribing by these doctors, Purdue continued to profit from it.

41. Purdue's sales persistence has paid off. In the Montana Medicaid Program, Purdue drugs constituted 75% of spending on branded Schedule II and III opioid analgesics between January 2011 and September 2017.

42. [redacted]



43. Sales visits are not Purdue's only marketing tactic. Purdue also used "key opinion leaders" ("KOLs")—experts in the field who were especially influential because of their reputations and seeming objectivity—to deliver paid talks and continuing medical education programs (or "CMEs") to prescribers that provided information about treating pain and the risks, benefits, and use of opioids. This was a strategy originally pioneered by Arthur Sackler, one of three Sackler brothers who founded Purdue, who is credited for first promoting pharmaceutical drugs directly to doctors, with clinical-looking ads in medical journals, visits to doctors' offices, and prominent medical thought-leaders. KOLs received substantial funding and research grants

from Purdue, and the CMEs were often sponsored by Purdue—giving Purdue considerable influence over the messenger, the message, and the distribution of the program. Only doctors who were supportive of the use and safety of opioids for chronic pain received these funding and speaking opportunities. One leading KOL, Dr. Russell Portenoy, subsequently acknowledged that he gave lectures on opioids that reflected "misinformation" and were "clearly the wrong thing to do."[10]

44. In addition to talks and CMEs, these KOLs served on the boards of patient advocacy groups and professional associations, such as the American Pain Foundation and the American Pain Society, that were also able to exert greater influence because of their seeming independence. Purdue and other pharmaceutical companies exerted influence over these groups by providing major funding directly to them, as well. These "front groups" for the opioid industry put out patient education materials and treatment guidelines that supported the use of opioids for chronic pain, overstated their benefits, and understated their risks. In many instances, Purdue distributed these publications to prescribers or posted them on its website.

45. In addition, Purdue employees and KOLs identified, funded, published, and disseminated research that was designed to assist Purdue's marketing efforts and skewed or misreported the scientific evidence. For example, to substantiate its claims that opioids were rarely addictive, Purdue included in promotional and educational materials a cite to the prestigious *New England Journal of Medicine*, but failed to disclose its source was a letter to the editor. Drug companies used this letter to conclude that their new opioids were not addictive, "[b]ut that's not in any shape or form what we suggested in our letter," according to one of its

[10] Thomas Catan and Evan Perez, "A Pain-Drug Champion Has Second Thoughts," *The Wall Street Journal* (Dec. 17, 2012, https://www.wsj.com/articles/SB10001424127887324478304578173342657044604.

authors, Dr. Hershel Jick.[11] A recent analysis in the *Journal* in June 2017 found that citation of the letter significantly increased after the introduction of OxyContin and "contributed to the North American opioid crisis by helping to shape a narrative that allayed prescribers' concerns about the risk of addiction associated with long-term opioid therapy."[12] It continued to be widely cited in literature and materials available until the present.

46. Neither these third-party, unbranded materials, nor the marketing messages or scripts relied on by Purdue's sales representatives, were reviewed or approved by the U.S. Food & Drug Administration ("FDA"). All of the messages described in this Complaint were disseminated to Montana prescribers and patients through sales representative visits, medical education programs, websites, and other sources.

VI. MOST DANGEROUSLY, PURDUE MISREPRESENTS THE RISK THAT CHRONIC PAIN PATIENTS WILL BECOME ADDICTED TO ITS OPIOIDS.

47. Purdue misrepresents, even today, to Montana doctors and patients the risk of opioid addiction. Specifically, Purdue affirmatively misrepresents that: (a) pain patients do not become addicted to opioids; (b) its long-acting opioids are steady-state and less addictive; (c) doctors can identify and manage the risk of addiction; (d) patients who seem addicted are merely "pseudoaddicted," and should be treated with more opioids; (e) opioid addiction is the product not of narcotic opioids, but problem patients and doctors; and (f) opioid abuse and addiction manifests in snorting and injecting the drugs, rather than in oral abuse. In addition, Purdue failed

[11] Taylor Haney and Andrea Hsu, "Doctor Who Wrote 1980 Letter on Painkillers Regrets That It Fed The Opioid Crisis," *National Public Radio* (Jun. 16, 2017) http://www.npr.org/sections/health-shots/2017/06/16/533060031/doctor-who-wrote-1980-letter-on-painkillers-regrets-that-it-fed-the-opioid-crisi.

[12] *Id.*

to disclose to Montana prescribers and patients the risks of addiction to, and withdrawal from, its opioids.

A. Misrepresenting or failing to disclose the risk of addiction.

48. Purdue's sales representatives often omitted from their sales conversations with Montana prescribers any discussion of the risk of addiction from long-term use of opioids. This failure to disclose the risk of addiction—an adverse effect that Purdue knew was material—was deceptive in its own right, but especially in light of Purdue's past misrepresentations regarding the risk of addiction, which Purdue failed to correct.

49. Moreover, Purdue continued to affirmatively misrepresent that pain patients would not become addicted to opioids. Montana prescribers were told that, although OxyContin is a narcotic, patients being treated for chronic pain will not become addicted and that its drugs, used properly, were safe.

50. Purdue also disseminated misleading information about opioids and addiction through the front group American Pain Foundation ("APF"), over which Purdue exercised control. *A Policymaker's Guide to Understanding Pain & Its Management*, a 2011 APF publication that Purdue sponsored, claimed that pain had been "undertreated" due to "[m]isconceptions about opioid addiction." This guide also repurposed Purdue's pre-2007 assertion, now claiming that "less than 1% of children treated with opioids become addicted," which would help support OxyContin's market for children 11-years and older—an indication Purdue sought and received in 2015. A *Policymaker's Guide* also perpetuated the concept of pseudoaddiction. On information and belief, based on Purdue's close relationship with APF and the periodic reports APF provided to Purdue about the project, Purdue had editorial input into *A Policymaker's Guide*. It is still available to Montana prescribers online.

51. Purdue also maintained a website from 2008 to 2015, *In the Face of Pain,* which downplayed the risks of chronic opioid therapy. Purdue deactivated this website in October 2015 following an investigation by the New York Attorney General. While the website discussed opioids and side-effects from their use and the *fear* of addiction (as a barrier to use), it *never*, anywhere on the website, disclosed the risk of addiction to opioids. At the same time, the website contained testimonials from several dozen physicians speaking positively about opioids. Eleven of these advocates received a total of $231,000 in payments from Purdue from 2008 to 2013—a fact notably omitted from the website.

52. As before the 2007 settlements and criminal pleas, Purdue continues to tell Montana doctors in sales visits that its long-acting opioids are "steady-state," with no peaks and troughs. This promise of steady-release implies (and is understood by prescribers to mean) that Purdue's opioids are less addictive because they do not trigger the euphoric rush and crash that fuel drug cravings.

53. Purdue sales representatives also failed to disclose to Montana prescribers the difficulty of opioid withdrawal. Discontinuing or delaying opioids can cause agonizing physical and psychological effects that can last for weeks, including anxiety, nausea, headaches, painful muscle cramps, and delirium, among others. Withdrawal symptoms can leave many patients unwilling or unable to give up opioids and heightens the risk of addiction. In the words of one physician, "I see all these people who are convinced they are one of the 'legitimate' pain patients. They're on a massive dose of opioids and they're telling me they need this medication,

which is clearly doing them *harm*. For many of them, the primary benefit of therapy, at this point, is not going into withdrawal." (Emphasis in original).[13]

B. Overstating the ability of doctors to manage the risk of addiction and failing to disclose the lack of evidence that these strategies work.

54. Upon information and belief, Purdue sales representatives conveyed to doctors that they can screen out patients at high risk of addiction through screening tools, urine tests and patient contracts, and safely prescribe to their other "appropriate" patients. Upon information and belief, Purdue also promoted screening tools as a reliable means to manage addiction risk in CME programs and scientific conferences attended by or available to Montana prescribers. Purdue failed to disclose the lack of evidence that these risk management strategies mitigate addiction risk.

55. Upon information and belief, Purdue shared its *Partners Against Pain* "Pain Management Kit," which contains several "drug abuse screening tools" and CDs with catalogues of Purdue materials, which included these tools, with Montana prescribers.

56. Purdue also sponsored an online CME program taught by Dr. Lynn Webster, another KOL who the company also funded, titled *Managing Patient's Opioid Use: Balancing the Need and Risk*. This presentation deceptively instructed that screening tools, patient agreements, and urine tests prevented "overuse of prescriptions" and "overdose deaths." The CME currently is available online to Montana prescribers.[14] Upon information and belief, it has

[13] Patrick Radden Keefe, "The Family That Built an Empire of Pain," *The New Yorker* (Oct. 30, 2017), https://www.newyorker.com/magazine/2017/10/30/the-family-that-built-an-empire-of-pain.
[14] Emerging Solutions in Pain, "Managing Patient's Opioid Use: Balancing the Need and the Risk," http://www.emergingsolutionsinpain.com/ce-education/opioid-management?option=com_continued&view=frontmatter&Itemid=303&course=209 (last visited Nov. 30, 2017).

been available online for approximately six years and it has been viewed by additional Montana prescribers since it was first broadcast in September 2011.

57. Another Purdue-funded CME, *Chronic Pain Management and Opioid Use: Easing Fears, Managing Risks, and Improving Outcomes*, deceptively instructs doctors that, through the use of screening tools, more frequent refills, and other techniques, high-risk patients showing signs of addictive behavior can be treated safely with opioids. Upon information and belief, this CME was presented live on October 11, 2012, by webinar available in Montana, and the CME currently is available online to Montana prescribers. Upon information and belief, it has been available online for approximately five years and it has been viewed by additional Montana prescribers since its live broadcast.

58. [redacted]

C. Promoting the unsubstantiated concept of pseudoaddiction to discount signs of addiction.

59. Purdue also deceptively advised doctors to ignore signs of addiction as the product of "pseudoaddiction." The theory of pseudoaddiction counseled that signs of addiction, such as asking for a drug by name or seeking early refills, reflect undertreated pain that should be addressed with more opioids—the medical equivalent of fighting fire with gasoline. Purdue deceptively described pseudoaddiction as an accepted scientific concept, although the term was coined by a single doctor named David Haddox, who was later hired by Purdue, and based on the observation of a single patient. In *Providing Relief, Preventing Abuse,* a pamphlet published by Purdue for prescribers and law enforcement beginning in 2011, Purdue described

pseudoaddiction as a term that "has emerged in the literature to describe the inaccurate interpretation of [drug-seeking] behaviors in patients who have pain that has not been effectively treated."

60. Sales representatives in Montana promoted pseudoaddiction to doctors. [redacted]

61. [redacted]

62. Purdue promoted pseudoaddiction through at least 2013 on its website, *Partners Against Pain.*[15]

63. Purdue also sponsored the publication *Responsible Opioid Prescribing* (2007), which taught that patient behaviors such as "requesting drugs by name, "demanding or

[15] *Partners Against Pain* consists of both a website, styled as an "advocacy community" for pain care, and education resources distributed to prescribers by Purdue sales representatives. It has existed since at least the early 2000s and has been a vehicle for Purdue to downplay the risks of addiction from long-term opioid use. One early pamphlet, for example, answered concerns about OxyContin's addictiveness by claiming: "Drug addiction means using a drug to get 'high' rather than to relieve pain. You are taking opioid pain medication for medical purposes. The medical purposes are clear and the effects are beneficial, not harmful."

manipulative behavior," seeing more than one doctor to obtain opioids, and hoarding, are all signs of pseudoaddiction. [redacted]

D. Falsely portraying addiction as a problem of opioid abuse and diversion, not opioid use.

64. In addition to deceptively ascribing signs of addiction to pseudoaddiction, Purdue falsely portrayed "true" addiction in its narrowest form. *Providing Relief, Preventing Abuse* shows pictures of the signs of injecting or snorting opioids—track marks and perforated nasal septa—under the heading "Indications of Possible Drug Abuse." Purdue knew that these extremes are uncommon; users far more typically become dependent and addicted by swallowing intact pills. According to briefing materials Purdue submitted to the FDA in October 2010, OxyContin was used non-medically by injection as little as 4% of the time.

65. These skewed depictions misleadingly reassured doctors that, in the absence of these extreme signs, they need not worry that their patients are abusing, or addicted to, opioids. [redacted]

66. Purdue used its involvement in the College on the Problems of Drug Dependence ("CPDD"), which provides training and support to addiction treatment professionals, to promote the idea that addiction risk can be managed. A Purdue employee served on the CPDD board of directors and Purdue has been a frequent presenter at CPDD conferences. One of Purdue's consistent themes was that "bad apple" patients, not opioids, are the source of the addiction crisis, and that once those patients are identified, doctors can safely prescribe opioids. Hundreds

of addiction treatment specialists from across the country attended these conferences. Upon information and belief, the attendees included Montana prescribers.

67. More generally, Purdue had no basis to assert that addiction is the result of patients who manipulate either the drugs or their doctors. Patients who "doctor-shop," that is, visit multiple prescribers to obtain opioid prescriptions, are responsible for roughly 2% of opioid prescriptions.[16] The epidemic of opioid overprescribing is not, as Purdue often asserts, the result of problem patients or doctors.

E. Purdue's statements and omissions regarding the risk of addiction are contrary to, and unsupported by, scientific evidence.

68. Purdue's efforts to trivialize the risk of addiction were, and remain, at odds with the scientific evidence. Prescription opioids are, for the most part, "no less addictive than heroin."[17] Studies have shown that at least 8-12%, and as many as 30-40%, of long-term users of opioids experience problems with addiction.

69. Purdue's own evidence bears that out. [redacted]

70. More recently, in March 2016, after a "systematic review of the best available evidence," the CDC published the CDC Guideline for Prescribing Opioids for Chronic Pain

[16] National Institute on Drug Abuse, "Although Relatively Few, 'Doctor Shoppers' Skew Opioid Prescribing," (May 27, 2014) https://www.drugabuse.gov/news-events/nida-notes/2014/05/although-relatively-few-doctor-shoppers-skew-opioid-prescribing (last visited Nov. 30, 2017).

[17] Thomas R. Frieden and Debra Houry, New England Journal of Medicine, "Reducing the Risks of Relief—The CDC Opioid-Prescribing Guideline" at 1502 (Apr. 21, 2016).

("CDC Guideline"). The CDC Guideline noted that "[o]pioid pain medication use presents serious risks, including overdose and opioid use disorder" (a diagnostic term for addiction).[18] The CDC also emphasized that "continuing opioid therapy for 3 months substantially increases risk for opioid use disorder."[19]

71. There is no evidence that long-acting opioids, like Purdue's, are any less addictive than other opioids. In fact, long-acting opioids, including Hysingla and OxyContin, are, and have long been, Schedule II narcotics because of their "high potential for abuse" and "may lead to severe psychological or physical dependence." Purdue's representation that its long-acting opioids had fewer peaks and valleys or were less addictive was one of the deceptive statements acknowledged in its 2007 criminal plea and settlements, and it is no more true today.

72. The CDC Guideline also confirms the falsity of Purdue's claims about the utility of patient screening and management strategies in managing addiction risk. The Guideline notes that there are no studies assessing the effectiveness of risk mitigation strategies—such as screening tools or patient contracts—"for improving outcomes related to overdose, addiction, abuse, or misuse." The CDC Guideline recognizes that available risk screening tools "show *insufficient accuracy* for classification of patients as at low or high risk for [opioid] abuse or misuse" and counsels that doctors "should not overestimate the ability of these tools to rule out risks from long-term opioid therapy."[20]

73. No competent scientific source has validated the concept of pseudoaddiction. Not surprisingly, the CDC Guideline nowhere recommends attempting to provide more opioids to

[18] CDC Guideline at 2.

[19] *Id.* at 21.

[20] CDC Guideline at 28

patients exhibiting symptoms of addiction. Dr. Lynn Webster, a Purdue KOL, admitted that pseudoaddiction "is already something we are debunking as a concept" and became "too much of an excuse to give patients more medication. It led us down a path that caused harm."[21]

VII. PURDUE OVERSTATED THE BENEFITS OF OPIOIDS FOR CHRONIC PAIN WHILE HIDING THE LACK OF EVIDENCE SUPPORTING THEIR USE.

74. To convince Montana prescribers and patients that opioids should be used to treat chronic pain, Purdue also had to persuade them of a significant upside to long-term opioid use. But as the CDC Guideline makes clear, there is "*insufficient evidence* to determine the long-term benefits of opioid therapy for chronic pain."[22] In fact, the CDC found that "[n]o evidence shows a long-term benefit of opioids in pain and function versus no opioids for chronic pain with outcomes examined at least 1 year later" and that other treatments were more or equally beneficial and less harmful than long-term opioid use.[23] The few longer-term studies of opioid use had "consistently poor results," and "several studies have showed that opioids for chronic pain may actually worsen pain and functioning . . . ."[24] As a result, the CDC recommends that opioids be used not in the first instance, but only after prescribers have exhausted alternative treatments.

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[21] John Fauber, "Painkiller Boom Fueled by Networking," Milwaukee Wisc. J. Sentinel, Feb. 18, 2012.

[22] *Id.* at 10.

[23] *Id.* at 9.

[24] Thomas R. Frieden and Debra Houry, New England Journal of Medicine, "Reducing the Risks of Relief—The CDC Opioid-Prescribing Guideline" at 1501-02 (Apr. 21, 2016).

A. Failing to disclose the lack of evidence supporting the use of opioids long-term for chronic pain.

75. Nevertheless, Purdue touted the purported benefits of long-term opioid use, while falsely and misleadingly suggesting that these benefits were supported by scientific evidence. Moreover, based on interviews with Montana prescribers, Purdue sales representatives promoted its drugs for chronic pain, but did not disclose in their sales conversations the lack of evidence supporting long-term use.

76. Two professional medical membership organizations, the American Pain Society ("APS") and the American Academy of Pain Medicine ("AAPM"), each received substantial funding from Purdue.[25] Upon information and belief, based on their funding and the involvement of Purdue KOLs in leadership roles, Purdue was able to exercise considerable influence over their work on opioids. Both organizations issued a consensus statement in 1997, *The Use of Opioids for the Treatment of Chronic Pain*, that endorsed opioids to treat chronic pain and claimed that the risk that patients would become addicted to opioids was low. The co-author of the statement, Dr. David Haddox (also responsible, as noted above, for coining the term "pseudoaddiction"), was at the time a Purdue KOL and later became a senior executive for the company. Dr. Russell Portenoy, a pain management specialist who received Purdue research grants and was a Purdue consultant, was the sole consultant. The consensus statement remained on AAPM's website until 2011.

77. AAPM and APS issued treatment guidelines in 2009 ("AAPM/APS Guidelines") which continued to recommend the use of opioids to treat chronic pain. Treatment guidelines were particularly important to Purdue in securing acceptance for chronic opioid therapy. Such

[25] [redacted]

guidelines are relied upon by doctors, especially general practitioners and family doctors who have no specific training in treating chronic pain. Six of the twenty-one panel members who drafted the AAPM/APS Guidelines, including Dr. Portenoy, received support from Purdue, and another eight received support from other opioid manufacturers.

78. The AAPM/APS Guidelines promote opioids as "safe and effective" for treating chronic pain. The panel made "strong recommendations" despite "low quality of evidence" and concluded that the risk of addiction is manageable for patients, even with a prior history of drug abuse. One panel member, Dr. Joel Saper, Clinical Professor of Neurology at Michigan State University and founder of the Michigan Headache & Neurological Institute, resigned from the panel because of his concerns that the Guidelines were influenced by contributions that drug companies, including Purdue, made to the sponsoring organizations and committee members. Dr. Gilbert Fanciullo, a retired professor at Dartmouth College's Geisel School of Medicine who also served on the panel, described them as "skewed" by Purdue and other drug companies and "biased in many important respects," including its high presumptive maximum dose, lack of suggested mandatory urine toxicology testing, and claims of a low risk of addiction.

79. The AAPM/APS Guidelines are still available online, were reprinted in the *Journal of Pain* and have influenced not only treating physicians and chemical dependency treatment providers, but also the body of scientific evidence on opioids. According to Google Scholar, they have now been cited 1,647 times in academic literature.

80. Purdue also published misleading studies to enhance the perception that opioids are effective long-term for chronic pain conditions. For example, one study asserts that OxyContin is safe and effective for the chronic pain condition osteoarthritis. The study, sponsored by Purdue, related to a chronic condition, but only provided opioids for 30 days. The

authors acknowledge that the "results . . . should be confirmed in trials of longer duration to confirm the role of opioids in a chronic condition such as OA [osteoarthritis]."[26] Yet, the authors conclude that "[t]his clinical experience shows that opioids were well tolerated with only rare incidence of addiction and that tolerance to the analgesic effects was not a clinically significant problem when managing patients with opioids long-term."[27] This statement is not supported by the data—a substantial number of patients dropped out because of adverse effects; there was no reported data regarding addiction; and the study was not long-term. Another Purdue study of a chronic pain condition only evaluated patients over seven days, but found oxycodone effective in its treatment.[28]

B. Overstating opioids' effect on patients' function and quality of life.

81. Purdue also claimed—without evidence—through its sales representatives and other materials disseminated in Montana, that long-term opioid use would help to improve patients' function and quality of life and get them back to work and to their lives.

82. Purdue and Purdue-sponsored materials distributed or made available in Montana reinforced this message. The 2011 publication *A Policymaker's Guide* falsely claimed that "multiple clinical studies have shown that opioids are effective in improving daily function and quality of life for chronic pain patients." A series of medical journal advertisements for

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[26] Jacques R. Caldwell, *et al.*, *Treatment of Osteoarthritis Pain with Controlled Release Oxycodone or Fixed Combination Oxycodone Plus Acetaminophen Added to Nonsteroidal Antiinflammatory Drugs: A Double Blind, Randomized, Multicenter, Placebo Controlled Trial*, 266.4 Journal of Rheumatology 862-869 (1999).

[27] *Id.*

[28] Martin E. Hale, Roy Fleischmann, Robert Salzman, James Wild, Tad Iwan, Ruth E. Smanton, Robert F. Kaiko, and Peter G. Lacouture, *Efficacy and Safety of Controlled-Release Versus Immediate-Release Oxycodone: Randomized, Double-Blind Evaluation in Patients with Chronic Back Pain*, The Clinical Journal of Pain, Sep. 1, 1999, https://www.ncbi.nlm.nih.gov/pubmed/10524470.

OxyContin in 2012 presented "Pain Vignettes"—case studies featuring patients with chronic pain conditions—that implied functional improvement. For example, one advertisement described a "writer with osteoarthritis of the hands" and implied that OxyContin would help him work more effectively.

83. Purdue sponsored the Federation of State Medical Board's ("FSMB's") *Responsible Opioid Prescribing* (2007), which taught that relief of pain itself improved patients' function. *Responsible Opioid Prescribing* explicitly describes functional improvement as the goal of a "long-term therapeutic treatment course." This publication claimed that because pain had a negative impact on a patient's ability to function, relieving pain—alone—would "reverse that effect and improve function." However, the truth is far more complicated; functional improvements made from increased pain relief can be offset by a number of problems, including addiction. [redacted]

84. Likewise, Purdue's claims that long-term use of opioids improves patient function and quality of life are unsupported by clinical evidence. As noted above, there are no controlled studies of the use of opioids beyond 16 weeks, and there is no evidence that opioids improve patients' pain and function long-term. On the contrary, the available evidence indicates opioids may worsen patients' health and pain. Increasing the duration of opioid use is strongly associated with an increasing prevalence of mental health conditions (depression, anxiety, post-traumatic stress disorder, and substance abuse), increased psychological distress, and greater health care utilization.

85. As one pain specialist observed, "opioids may work acceptably well for a while, but over the long term, function generally declines, as does general health, mental health, and

social functioning. Over time, even high doses of potent opioids often fail to control pain, and these patients are unable to function normally."[29] Studies of patients with lower back pain and migraine headaches, for example, have consistently shown that patients experienced deteriorating function over time, as measured by ability to return to work, physical activity, pain relief, rates of depression, and subjective quality-of-life measures. Analyses of workers' compensation claims have found that workers who take opioids are almost four times more likely to reach costs over $100,000, stemming from greater side effects and slower returns to work.

86. Assessing existing science, the CDC Guideline found that there was "[n]o evidence show[ing] a long-term benefit of opioids in pain and function versus no opioids for chronic pain with outcomes examined at least 1 year later"[30] and advised that "there is no good evidence that opioids improve pain or function with long-term use."[31] Similarly, the FDA has warned other opioid product manufacturers that claims of improved function and quality of life were misleading.[32] The CDC also noted that the risks of addiction and death "can cause distress and inability to fulfill major role obligations."[33] In that vein, a recent study by Princeton

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[29] Andrea Rubinstein, *Are We Making Pain Patients Worse?*, Sonoma Med. (Fall 2009), http://www.nbcms.org/about-us/sonoma-county-medical-association/magazine/sonomamedicine-are-we-making-pain-patients-worse?

[30] CDC Guideline at 15.

[31] *Id.* at 20.

[32] *See,* Warning Letter from Thomas Abrams, Dir., FDA Div. of Mktg., Adver., & Commc'ns, to Doug Boothe, CEO, Actavis Elizabeth LLC (Feb. 18, 2010), (rejecting claims that Actavis' opioid, Kadian, had an "overall positive impact on a patient's work, physical and mental functioning, daily activities, or enjoyment of life."); Warning Letter from Thomas Abrams, Dir., FDA Div. of Mktg., Adver., & Commc'ns, to Brian A. Markison, Chairman, President and Chief Executive Officer, King Pharmaceuticals, Inc. (March 24, 2008), (finding the claim that "patients who are treated with [Avinza (morphine sulfate ER)] experience an improvement in their overall function, social function, and ability to perform daily activities . . . has not been demonstrated by substantial evidence or substantial clinical experience."). These warning letters were available to Purdue on the FDA website.

[33] CDC Guideline at 2.

economist Alan Krueger found that opioids may be responsible for roughly 20% of the decline in workforce participation among prime-age men and 25% of the drop for women.[34]

87. The CDC Guideline concluded that "[w]hile benefits for pain relief, function and quality of life with long-term opioid use for chronic pain are uncertain, risks associated with long-term opioid use are clearer and significant."[35] According to Dr. Tom Frieden, then Director of the CDC, "for the vast majority of patients, the known, serious, and too-often-fatal risks far outweigh the unproven and transient benefits [of opioids for chronic pain]."[36] As one doctor noted, the widespread, long-term use of opioids "was an experiment on the population of the United States. It wasn't randomized, it wasn't controlled, and no data was collected until they started gathering death statistics."

88. [redacted]

C. Omitting or mischaracterizing adverse effects of opioids.

89. In materials Purdue produced, sponsored, or controlled, Purdue omitted known risks of chronic opioid therapy and emphasized or exaggerated risks of competing products so that prescribers and patients would favor opioids over other therapies such as over-the-counter

[34] Alan B. Krueger, *Where Have All the Workers Gone? An Inquiry into the Decline of the U.S. Labor Force Participation Rate*, Brookings Papers on Economic Activity Conference Draft (Aug. 26, 2017).

[35] CDC Guideline at 18.

[36] Thomas R. Frieden and Debra Houry, New England Journal of Medicine, "Reducing the Risks of Relief—The CDC Opioid-Prescribing Guideline" (Apr. 21, 2016).

acetaminophen or nonsteroidal anti-inflammatory drugs (or NSAIDs, like ibuprofen), which do not impose a risk of addiction. None of these claims were corroborated by scientific evidence.

90. In addition to failing to disclose in promotional materials the risks of addiction, abuse, overdose, and respiratory depression, Purdue also routinely omitted other significant risks from long-term opioid use, including: hyperalgesia, a "known serious risk associated with chronic opioid analgesic therapy," in which the patient becomes more sensitive to certain painful stimuli over time; hormonal or endocrine dysfunction; decline in immune function; mental clouding, confusion, and dizziness; increased falls and fractures in the elderly; neonatal abstinence syndrome (when an infant exposed to opioids prenatally painfully withdraws from the drugs after birth); and potentially fatal interactions with alcohol or benzodiazepines, which are used to treat post-traumatic stress disorder and anxiety that are often also used by pain patients.

91. Purdue sponsored APF's *Treatment Options: A Guide for People Living with Pain* (2007) counseled patients that opioids differ from NSAIDs in that they have "no ceiling dose" and are therefore the most appropriate treatment for severe pain. The publication inaccurately attributes 10,000 to 20,000 deaths annually to NSAIDs (the actual figure is approximately 3,200, far fewer than from opioids). This publication also warned that risks of NSAIDs increase if "taken for more than a period of months," with no corresponding warning about opioids.

92. Purdue sponsored a CME program, *Overview of Management Options*, published by the American Medical Association in 2003, 2007, 2010, and 2013, and discussed further below. The CME was edited by Dr. Russell Portenoy, among others, and taught that NSAIDs and other drugs, but not opioids, are unsafe at high doses.

93. These omissions regarding adverse side-effects are significant and material to patients and prescribers. A Cochrane Collaboration review of evidence relating to the use of opioids for chronic pain found that 22% of patients in opioid trials dropped out before the study began because of the "intolerable effects" of opioids.[37] Moreover, the CDC, in its evidence review, did not find evidence that opioids were more effective for pain reduction than NSAIDs for back pain or antidepressants for neuropathic pain (typically, nerve pain), and found that non-opioids were better tolerated and better at improving physical function, with little or no risk of addiction and lower risks of overdose and death.[38]

94. Purdue's misrepresentations were effective in increasing its own sales and driving down those of this alternative, less risky and less costly treatment. A study of 7.8 million doctor visits nationwide between 2000 and 2010 found that opioid prescriptions increased from 11.3% to 19.6% of visits while NSAID and acetaminophen prescriptions fell from 38% to 29%.

VIII. PURDUE PROMOTED THE USE OF OPIOIDS IN EVER-HIGHER DOSES WITHOUT DISCLOSING THE GREATER RISKS.

95. Purdue falsely claimed to Montana prescribers and consumers that opioids could be taken in ever-increasing strengths to obtain pain relief, without disclosing that higher doses increased the risk of addiction and overdose. This was particularly important because patients on opioids for more than a brief period develop tolerance, requiring increasingly high doses to achieve pain relief. Purdue needed to generate this comfort level among doctors to ensure the doctors maintained patients on the drugs.

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[37] Meredith Noble M, *et al.*, *Long-term Opioid Management for Chronic Noncancer Pain (Review)*, Cochrane Database of Systematic Reviews, Issue 1, 11 (2010).

[38] Thomas R. Frieden and Debra Houry, New England Journal of Medicine, "Reducing the Risks of Relief—The CDC Opioid-Prescribing Guideline" at 1503 (Apr. 21, 2016).

96. Through at least June 2015, Purdue's *In the Face of Pain* website promoted the notion that if a patient's doctor did not prescribe a sufficient dose of opioids, the patient should find a doctor who would.

97. *A Policymaker's Guide* taught that dose escalations are "sometimes necessary," but did not disclose the risks from high dose opioids. Upon information and belief, Purdue collaborated with APF to create this publication. This publication is still available online.

98. The Purdue-sponsored online CME, *Overview of Management Options*, discussed above, instructed physicians that NSAIDs are unsafe at high doses (because of risks to patients' kidneys), but did not disclose risks from opioids at high doses.

99. [redacted] Not only does this statement raise issues with Purdue's claims regarding 12-hour dosing (see Section IX, below), but this advice was not accompanied by warnings regarding increased risk of addiction associated with increased doses.

100. Purdue's assertions and omissions are contrary to scientific evidence. Patients receiving high doses of opioids (*e.g.*, doses greater than 100 mg morphine equivalent dose ("MED") per day) as part of long-term opioid therapy are three to nine times more likely to suffer overdose from opioid-related causes than those on low doses.[39]

[39] Kate M. Dunn, *et al.*, *Opioid Prescriptions for Chronic Pain and Overdose: A Cohort Study*, 152(2) Annals of Internal Med. 85-92 (Jan. 19, 2010). Most overdoses were medically serious and 12% were fatal.

[redacted]

37. To deliver these messages, Purdue inundated Montana prescribers with promotional sales visits. From May 8, 2007 to September 14, 2017, Purdue made [redacted] visits to [redacted] prescribers or pharmacies in [redacted] communities across Montana, for an average of more than [redacted] interactions every workday.

38. The ten prescribers most frequently visited by Purdue were seen an average of once every [redacted]. The most visited doctor, a physician in Billings, received [redacted] visits from Purdue. But advertising messages were not the only thing that Purdue sales representatives provided to doctors. Another doctor in Billings, for example, received payments or items of value worth more than $16,500 over approximately three years from Purdue sales representatives. [redacted]

[redacted]

101. The CDC Guideline concludes that the "[b]enefits of high-dose opioids for chronic pain are not established"[40] while "[o]verdose risk increases in a dose-response manner . . . ."[41] That is why the CDC advises doctors to "avoid increasing doses" above 90 mg MED.[42]

102. In Montana, Purdue's sales depended upon high dose use. In Medicaid data from August 2010 to September 2017, 73% of OxyContin revenue came from patients with average morphine equivalent doses ("MED") in excess of 90 mg MED.

103. [redacted]

[40] CDC Guideline at 19. The 2016 CDC Guideline reinforces earlier findings announced by the FDA. In 2013, the FDA acknowledged "that the available data do suggest a relationship between increasing opioid dose and risk of certain adverse events." For example, the FDA noted that studies "appear to credibly suggest a positive association between high-dose opioid use and the risk of overdose and/or overdose mortality."

[41] CDC Guideline.

[42] CDC Guideline at 16.

IX. PURDUE MISLEADINGLY PROMOTED OXYCONTIN AS SUPPLYING 12 HOURS OF PAIN RELIEF WHEN PURDUE KNEW THAT, FOR MANY PATIENTS, IT DID NOT.

104. To convince prescribers and patients to use OxyContin, Purdue misleadingly promoted the drug as providing 12 continuous hours of pain relief with each dose. In reality, OxyContin does not last for 12 hours in many patients, a fact Purdue has known since the product's launch. While OxyContin's FDA-approved label directs 12-hour dosing, Purdue sought that dosing frequency in order to maintain a competitive advantage over other opioids that required more frequent dosing. Yet Purdue has gone well beyond the label's instructions to take OxyContin every 12 hours by affirmatively claiming that OxyContin lasts for 12 hours and by failing to disclose that OxyContin fails to provide 12 hours of pain relief to many patients.

105. Since it was launched in 1996, OxyContin has been FDA-approved for twice-daily—"Q12"—dosing frequency. It was Purdue's decision to submit OxyContin for approval with 12-hour dosing. While the OxyContin label indicates that "[t]here are no well-controlled clinical studies evaluating the safety and efficacy with dosing more frequently than every 12 hours," that is because Purdue has conducted no such studies.

106. From the outset, Purdue leveraged 12-hour dosing to promote OxyContin as providing continuous, round-the-clock pain relief with the convenience of not having to wake to take a third or fourth pill. The 1996 press release for OxyContin touted 12-hour dosing as providing "smooth and sustained pain control all day and all night." But the FDA has never approved such a marketing claim. To the contrary, the FDA found in 2008, in response to a Citizen Petition by the Connecticut Attorney General, that a "substantial number" of chronic pain patients taking OxyContin experienced "end of dose failure"—*i.e.*, little or no pain relief at the end of the dosing period.

107. In fact, Purdue long has known, dating to its development of OxyContin, that the drug wears off well short of 12 hours in many patients. [redacted] This is consistent with the experience of Montana doctors, who have reported that for many patients, the drug did not last 12-hours.

108. End-of-dose failure renders OxyContin even more dangerous because patients begin to experience distressing psychological and physical withdrawal symptoms, followed by a euphoric rush with their next dose—a cycle that fuels a craving for OxyContin. For this reason, Dr. Theodore Cicero, a neuropharmacologist at the Washington University School of Medicine in St. Louis, has called OxyContin's 12-hour dosing "the perfect recipe for addiction."[43] Many patients will exacerbate this cycle by taking their next dose ahead of schedule or resorting to a rescue dose of another opioid, increasing the overall amount of opioids they are taking.

109. [redacted]

110. Without appropriate caveats, promotion of 12-hour dosing by itself is misleading because it implies that the pain relief supplied by each dose lasts 12 hours, which Purdue knew to

[43] Harriet Ryan, "*'You Want a Description of Hell?' OxyContin's 12-Hour Problem*", Los Angeles Times, May 5, 2016, http://www.latimes.com/projects/oxycontin-part1/.

be untrue for many, if not most, patients. FDA approval of OxyContin for 12-hour dosing does not give Purdue license to misrepresent the duration of pain relief it provides to patients; moreover, Purdue had a responsibility to disclose to prescribers what it knew about OxyContin's actual duration, regardless of any marketing advantage.

111. [redacted] Doctors understood Purdue's promotion to mean that OxyContin provides 12 hours of relief. [redacted]

112. Twelve-hour dosing also is featured in most OxyContin promotional pieces. [redacted] Upon information and belief, these pieces were distributed in Montana, and neither piece discloses that the pain relief from each 12-hour dose will last well short of 12 hours for many patients.

113. Purdue was also aware of some physicians' practice of prescribing OxyContin more frequently than 12 hours—a common occurrence, including by Montana prescribers. Purdue's promoted solution to this problem was to increase the dose, rather than the frequency, of prescriptions, even though higher dosing carries its own risks, as described in Section VIII. [redacted]

[redacted] Using higher doses also means that patients will experience higher highs and lower lows, increasing their craving for their next pill.

X. TO PROTECT ITS MARKET AND PROFITS, PURDUE MISREPRESENTED THE IMPACT OF ITS OPIOIDS IN REDUCING ABUSE AND ADDICTION.

114. With time, the toll of its highly successful marketing campaign became visible. Rather than remedy its prior deceptive marketing to rein in overprescribing, Purdue turned evidence of opioid abuse, overdose, and death into a new opportunity. In 2010, with the imminent expiration of its patent on OxyContin (and the prospect of generic competition for its marquee product), Purdue launched a reformulated OxyContin that was labeled "abuse-deterrent" because the pills are harder to crush and inject. Purdue promised doctors in Montana that its abuse-deterrent opioids were safer for patients. But Purdue knew that many users are still able to tamper with OxyContin, that oral abuse persists, and that many users turn to heroin—none of which it disclosed to doctors. By deceptively promoting its abuse-deterrent opioids as a strategy to cope with the epidemic of opioid addiction and death it helped unleash, Purdue has prolonged and deepened the crisis in Montana, persuading doctors and patients that they can continue to use opioids—so long as they are Purdue's.

115. Reformulated, Abuse Deterrent Formula ("ADF") OxyContin was approved by the FDA in April 2010. It was not until 2013 that the FDA, in response to a Citizen Petition filed by Purdue, permitted reference to the abuse-deterrent properties in the label. When Purdue launched Hysingla ER, extended-release hydrocodone in 2014, the product included similar abuse-deterrent properties.

116. The FDA noted in permitting ADF labeling that "the tamper-resistant properties will have no effect on abuse by the oral route (the most common mode of abuse)." Purdue's labels also acknowledge that abusers seek out the drugs because of their high likeability when

snorted, that the abuse deterrent properties can be defeated, and that they can be abused orally notwithstanding their abuse-deterrent properties, and do *not* indicate that ADF opioids prevent or reduce addiction, abuse, misuse, or diversion.

117. Purdue's national marketing campaign touted OxyContin's tamper-resistant properties as a primary message.[44] [redacted]

118. This is true in Montana, as well. Doctors report that abuse-deterrence is Purdue's primary marketing message in sales visits. Essentially all of Purdue's revenue in Montana is from its ADFs. Purdue claimed that its abuse-deterrent opioids are a sign that it is a more responsible company than in the past, and is aggressively trying to address the problem of opioid addiction and death. But Purdue's ADF marketing from sales representatives to Montana prescribers was itself deceptive, as Purdue marketed its ADF products as safe, when they are not. Purdue failed to disclose that ADF opioids are subject to oral abuse. Purdue also failed to disclose that ADF opioids simply shift some abuse to other opioids, such as heroin, with even worse outcomes. Purdue also knew or should have known, but did not disclose, that "reformulated OxyContin is not better at tamper resistance than the original OxyContin,"[45] and, in fact, is still regularly tampered with and abused.

119. Websites and message boards used by drug abusers, such as bluelight.org and reddit.com, report a variety of ways to tamper with OxyContin and Hysingla ER, including through grinding, microwaving then freezing, or drinking soda or fruit juice in which a tablet is dissolved. A publicly available Citizen Petition submitted to the FDA in 2016 by a drug

[44] *In re OxyContin,* 1:04-md-01603-SHS, (Russell Gasdia Tr. Sept. 2013), 994 F. Supp.2d at 416.

[45] *In re OxyContin*, 1:04-md-01603-SHS, Docket No. 613, Oct. 7, 2013 hr'g, Testimony of Dr. Mohan Rao, 1615:7-10; 1616:7-10.

manufacturing firm challenged Purdue's abuse-deterrent labeling based on the firm's ability to easily prepare OxyContin to be snorted or injected.

120. [redacted] *One-third* of the patients in a non-Purdue 2015 study defeated the ADF mechanism and were able to continue inhaling or injecting the drug. To the extent that the abuse of Purdue's ADF opioids was reduced, abuse simply shifted to other drugs such as heroin.

121. As in other areas, Purdue distorted its own research to support its promotional claims and to bury contradictory evidence. [redacted]

122. The CDC Guideline confirms that "*[n]o* studies" support the notion that "abuse deterrent technologies [are] a risk mitigation strategy for deterring or preventing abuse," noting that the technologies "do not prevent opioid abuse through oral intake, the most common route of opioid abuse, and can still be abused by nonoral routes."[46] The original FDA medical review of reformulated OxyContin explicitly stated in 2009 that "tamper-resistant properties will have no effect on abuse by the oral route (the most common mode of abuse)"—at the time estimated to be 72% of OxyContin abuse.[47] In the 2012 medical office review of Purdue's application to

[46] CDC Guideline at 22 (emphasis added).

[47] U.S. Food and Drug Administration Center for Drug Evaluation and Research, Medical Review of Application No. 22-272, http://www.accessdata.fda.gov/drugsatfda_docs/nda/2010/022272s000MedR.pdf.

include an abuse-deterrence claim in its label for OxyContin, the FDA noted that the overwhelming majority of deaths linked to OxyContin were associated with oral consumption, and that only 2% of deaths were associated with recent injection and only 0.2% with snorting the drug.

123. The FDA's Director of the Division of Epidemiology stated in September 2015—at the same time that Purdue was heavily promoting its abuse-deterrent formulations as safe and able to prevent abuse—that no data that she had seen suggested the reformulation of OxyContin "actually made a reduction in abuse," between continued oral abuse, shifts to injection of other drugs, and defeat of the ADF mechanism. Dr. Tom Frieden, then the Director of the CDC, reported that his staff could not find "any evidence showing the updated opioids [ADF opioids] actually reduce rates of addiction, overdoses, or death."

124. Purdue itself knew that claiming AD formulations reduces abuse was not supported by evidence. [redacted]

125. In 2015, claiming a need to further assess its data, Purdue abruptly withdrew its supplemental new drug application related to reformulated OxyContin one day before FDA staff were to release its assessment of the application. The staff review preceded an FDA advisory

committee meeting related to new studies by Purdue "evaluating the misuse and/or abuse of reformulated OxyContin" and whether those studies "have demonstrated that the reformulated product has a meaningful impact on abuse."[48] Given the absence of any public hearings or advisory meetings on the topic, it seems that Purdue still has not presented the data to the FDA, presumably because the data would not have supported claims that OxyContin's ADF properties reduced abuse or misuse.

126. [redacted]

127. Purdue's false and misleading marketing of the benefits of its ADF opioids preserved and expanded its sales by persuading doctors to write prescriptions for ADF opioids in the mistaken belief that they were safer. It also allowed prescribers to discount evidence of opioid addiction and abuse and attribute it to other, less safe opioids—*i.e.*, it allowed them to believe that while patients might abuse, become addicted to, or die from other, non-ADF opioids, Purdue's opioids did not carry that risk.

128. Purdue's misleading marketing preserved not only its price, but also its sales. Generic versions of OxyContin, which became available in February 2011, threatened to erode Purdue's market share and the price it could charge. Through a Citizen Petition, Purdue was able to secure a determination by the FDA in April 2013 that original OxyContin should be removed

[48] Meeting Notice, Joint Meeting of the Drug Safety and Risk Management Advisory Committee and the Anesthetic and Analgesic Drug Products Advisory Committee; Notice of Meeting, May 25, 2015, 80 FR 30686.

from the market as unsafe (lacking abuse-deterrent properties), and thus non-ADF generic copies could not be sold. As a result, Purdue extended its branded exclusivity for OxyContin until the patent protection on the abuse-deterrent coating expires. [redacted]

129. Purdue knew that its ADF marketing changed prescribers' perceptions of its opioids and their willingness to continue to prescribe them. [redacted]

130. According to law enforcement, doctors, and treatment providers, OxyContin continues to be widely abused, even after its reformulation, in Montana as elsewhere. It is still as sought after in illicit street sales; it is still snorted and injected; and it continues to result in overdoses and deaths.

XI. BY INCREASING OPIOID USE, PURDUE'S DECEPTIVE MARKETING FUELED THE OPIOID EPIDEMIC AND SIGNIFICANTLY HARMED MONTANA.

131. While Purdue and the Sacklers have profited greatly from increased sales of OxyContin and their other opioids, Montana and its taxpayers have borne its costs. These costs were imposed, in large measure, by Purdue, and should be borne by Purdue.

132. Opioids have had a particularly acute impact on Montana as a rural state. According to a recent report by the U.S. Department of Agriculture, "[r]ising rates of prescription medication abuse, especially of opioids, and the related rise in heroin-overdose deaths are contributing to this unprecedented rise in age-specific mortality rates after a century or more of steady declines. This trend, if it continues, will not only lower rural population but will increase what is known as the dependency ratio: the number of people likely to be not working (children and retirees) relative to the number of people likely to be wage earners (working-age adults)."[49] In Montana, the opioid epidemic has caused more than 700 overdose deaths in total since 2000—parents, spouses, and children who can never be brought back or made whole.

133. Multiple state agencies have had, and will have to, to develop programs and re-direct funding to address the opioid crisis created, in large measure, by Purdue. For example, in 2010, Montana began "Operation Medicine Cabinet," a prescription drug drop-off program, which now has nearly 50 permanent drop off sites around the State. The State also began in 2012 to operate Montana's Prescription Drug Registry, allowing providers and pharmacies to improve patient safety and monitor for signs of abuse/misuse or diversion. In addition, several agencies—including the Office of the Attorney General—have published opioid education materials or created websites to help the public understand the risks of opioid medication and prevent diversion.

[49] U.S. Dept. of Ag., Economic Information Bulletin 182, Rural America at a Glance (Nov. 2017).

134. The State's Department of Public Health and Human Services ("DPHHS") owns and operates a chemical dependency treatment center in Butte and a state psychiatric hospital in Warm Springs. Both facilities treat patients with opioid use disorder.

135. The Montana Department of Justice's Narcotics Bureau investigates high-level drug cases. Pill diversion has now become one of the biggest drivers of Narcotics Bureau investigations.

136. Likewise, the Montana Highway Patrol reports that drug arrests have increased dramatically over the past six years, and that since 2011, there have been 39 fatal automobile crashes involving opioid usage. According to the Montana Board of Crime Control, drug offenses have steadily risen since 2010, up 74%, to an all-time high. This rapid increase in drug offenses has put a substantial strain on law enforcement, jail, and court resources. Sheriffs and jail administrators in Montana estimate that over 90% of the individuals held were charged with addiction-related offenses. This contributes to increases in outside medical expenditures for the Department of Corrections.

137. The number of driving under the influence arrests involving drugs, rather than alcohol, prompted the Montana Highway Patrol to initiate a Drug Recognition Expert ("DRE") program in order to evaluate whether an impaired driver is under the influence of drugs. In addition, the State has incurred law enforcement costs directly related to opioid and heroin-related crimes, including the larger populations within Montana jails and correctional facilities and higher costs to treat opioid addiction among inmates that resulted.

138. The Child and Family Services Division of the Montana DPHHS also has incurred greater costs due to the opioid crisis. Over the last seven years, an average of more than

11% of DPHHS's foster care placements have involved prescription drug abuse by the child's parents or guardians.

139. The Office of Public Instruction also faces issues with drug abuse. Montana's children have the third-highest rate of prescription drug abuse in the country. Almost 23% of Montana high school seniors and almost 10% of children ages 12-17 report that they have abused prescription drugs.

140. In addition to increased program spending at its various state agencies, the State is injured by the opioid crisis through increased spending by Medicaid and the State healthcare programs for opioid prescriptions that should not have been written, doctor visits and toxicology screens that were not necessary, treatment for infants born addicted (see below), medication-assisted treatment and other support to those who become addicted, emergency room visits due to overdose, and treatment of opioid-induced constipation, Hepatitis C, sepsis, and endocarditis (all of which are related to intravenous drug use), among other opioid-related illnesses.

141. For every 1,000 babies born in Montana, nine of them require intensive care because they are addicted to drugs to which they were exposed in the womb. Their condition is known as neonatal abstinence syndrome ("NAS"). NAS is most commonly seen with opioid exposure, where it is known as neonatal opioid withdrawal syndrome ("NOWS"). Hospitalization charges are much higher for newborns with NAS ($34,000 versus $6,800), and between 60-77% of infants with NAS had Montana Medicaid as the primary payer. The charges to Montana Medicaid for their care was $14.1 million for 2009-2015.

142. Many of the victims of the opioid crisis, adult or child, will eventually turn to heroin, when they can no longer access or afford prescription opioids. Across the country, 80% of recent heroin users have previously used prescription opioids non-medically. Though still

small in absolute numbers, according to the Montana State Crime Lab, heroin-related offenses increased 1,557% from 2010 to 2015. Prior to the explosion in prescription opioid use, there were virtually no heroin-related drug offenses in the state.

143. The opioid epidemic also has hit Montana's Native American population especially hard. One former Blackfeet tribal leader stated: "The drug epidemic is our modern-day small pox."[50] Nationwide, drug overdose death rates from opioids are higher among Native Americans than the overall population. The Blackfeet Community Hospital reports that over 50% of the babies born there have been exposed to illicit substances. Likewise, hospitals on the Flathead Indian Reservation have reported that the percentage of newborns at risk for neonatal abstinence have increased from 15% in 2013 to 49% in 2016. In statewide comparisons of Native American and Non-Native American students in Montana, the percentages of students who used narcotic prescription drugs was higher in the Native American student population among every age group studied.

144. Montana is also incurring other costs related to overdose responses, naloxone spending for first responders, increased law enforcement spending, increased pretrial and post-trial incarceration costs, increased criminal defense costs, increased social services spending such as representing parents and children in neglect proceedings, and other costs and response measures needed to address the epidemic.

145. The State will need to incur significant additional expenses in the future to abate the public nuisance caused by Purdue's deceptive promotion. This will include, but is by no means limited to, the costs of continuing to dispose of unused prescriptions; re-educating doctors

[50] Rocky Mountain Tribal Epidemiology Center, Addressing Opioid Use in Pregnancy: Conversations and Next Steps in Blackfeet," www.rmtec.org/addressing-opioid-use-in-pregnancy/ (last visited Nov. 30, 2017).

and patients about the appropriate use of opioids and about the signs of addiction and the availability of treatment; and treatment for opioid addiction and overdose, including naloxone and medication-assisted addiction treatments, like buprenorphine.

XII. ALTHOUGH PURDUE KNEW THAT ITS MARKETING OF OPIOIDS WAS FALSE AND MISLEADING, THE COMPANY FRAUDULENTLY CONCEALED ITS MISCONDUCT.

146. Purdue has made, promoted, and profited from its misrepresentations about the risks and benefits of opioids for chronic pain even though it has known that its marketing was false and misleading. The history of opioids, as well as research and clinical experience over the last 20 years, established that opioids were highly addictive and responsible for a long list of very serious adverse outcomes. The FDA and other regulators warned Purdue of this, and likewise, Purdue paid hundreds of millions of dollars to address similar misconduct that occurred before 2008. Purdue had access to scientific studies, detailed prescription data, and reports of adverse events, including reports of addiction, hospitalization, and deaths—all of which made clear to Purdue the harms from long-term opioid use and that patients are suffering from addiction, overdoses, and death in alarming numbers. More recently, the FDA and CDC have issued findings based on existing medical evidence that conclusively expose the known falsity of Purdue's misrepresentations.

147. Notwithstanding this knowledge, at all times relevant to this Complaint, Purdue has taken steps to avoid detection of, and to fraudulently conceal, its unlawful, unfair, and deceptive conduct. Purdue has disguised its own role in the deceptive marketing of chronic opioid therapy by funding and working through biased science, unbranded marketing, third party advocates, and professional associations. Purdue has purposely hidden behind the assumed credibility of these sources and relied on them to establish the accuracy and integrity of Purdue's

false and misleading messages about the risks and benefits of long-term opioid use for chronic pain. Purdue has masked or never disclosed its role in shaping, editing, and approving the content of this information. Purdue also has distorted the meaning or import of studies it cited and offered them as evidence for propositions the studies did not support. Purdue thus successfully concealed from the medical community, patients, and the State facts sufficient to arouse suspicion of the claims that the State now asserts. The State did not know of the existence or scope of Purdue's deception and could not have acquired such knowledge earlier through the exercise of reasonable diligence.

XIII. CLAIMS FOR RELIEF

COUNT ONE

VIOLATIONS OF THE UNFAIR TRADE PRACTICES AND CONSUMER PROTECTION ACT

148. The State incorporates the preceding paragraphs as if fully set forth herein.

149. Purdue is engaged in trade or commerce in the State of Montana.

150. Purdue violated the Unfair Trade Practices and Consumer Protection Act, Mont. Code Ann. § 30-14-103, and its implementing regulations, by engaging in unfair and deceptive trade practices through its marketing and advertising of opioids. These violations include:

a. Purdue made false representations as to the source, sponsorship, approval, or certification of merchandise, in violation of Admin. Rules Mont. § 23.19.101(1)(b);

b. Purdue made false representations as to the characteristics, ingredients, uses, benefits, alterations or quantities of merchandise, in violation of Admin. Rules Mont. § 23.19.101(1)(e); and

c. Purdue represented that merchandise is of a particular standard, style, or model, when it was of another, in violation of Admin. Rules Mont. § 23.19.101(1)(g).

151. Purdue's representations and omissions, aimed at both physicians and consumers, were deceptive because they had a tendency or capacity to deceive and were material to doctors' and patients' decisions to use Purdue's products. The violations include, but are not limited to, deceptively and misleadingly:

a. Denying that pain patients would become addicted to opioids;

b. Omitting that opioids are highly addictive and may result in overdose or death;

c. Claiming that signs of addiction were "pseudoaddiction" reflecting undertreated pain, and should be responded to with *more* opioids;

d. Claiming that the risk of addiction to opioids could be managed and avoided through risk screening tools and other strategies;

e. Claiming that opioid doses can be increased, without disclosing the greater risks of addiction, other injury, or death at higher doses;

f. Misleadingly comparing opioids and NSAIDs, including overstating the risks of NSAIDs and citing risks of NSAIDs without disclosing risks of opioids;

g. Claiming that opioids are an appropriate treatment for chronic pain, and failing to disclose the lack of long-term evidence for their use;

h. Claiming chronic opioid therapy would improve patients' function and quality of life;

i. Promoting OxyContin as providing a full 12 hours of pain relief, and failing to disclose that it does not for many patients;

j. Claiming abuse-deterrent opioids reduce addiction and abuse and are safer than other opioids, and failing to disclose that they do not limit oral abuse, can be defeated with relative ease, and may increase overall abuse;

k. Promoting itself as a company that encourages and assists law enforcement while not reporting suspicious prescribing to law enforcement;

l. Promoting opioids as superior to other competing analgesics, such as NSAIDs, and exaggerating the risks of NSAIDs while ignoring risks of adverse effects of opioids; and

m. Omitting other material facts that deceived consumers by virtue of Purdue's other representations to Montana consumers, including other adverse effects from opioid use.

152. Purdue's acts or practices also were unfair, as they offended established public policy and were either immoral, unethical, oppressive, unscrupulous, or substantially injurious to consumers and the State. Such practices included all actions alleged in the preceding paragraphs of this Complaint, and the following:

a. Encouraging the use of opioid medications as a first-line treatment for chronic pain, in conflict with the professional standard of care in Montana;

b. Encouraging the use of opioid medications as a first-line treatment for chronic pain, in conflict with the CDC Guideline for Prescribing Opioids for Chronic Pain; and

c. Encouraging the use of opioid medications as a first-line treatment for chronic pain, in conflict with public policy efforts in the State of Montana to reduce the use of opioid medications and curb the opioid epidemic.

153. Purdue's acts and practices described in this Complaint were willful and were knowingly directed toward a population that included numerous older persons.

COUNT TWO

VIOLATIONS OF THE MONTANA FALSE CLAIMS ACT

154. The State incorporates the preceding paragraphs as if fully set forth herein.

155. Section 17-8-403 of the Montana False Claims Act provides:

> (1) Except as provided in subsection (2), a person is liable to a governmental entity for a civil penalty of not less than $5,500 and not more than $11,000 for each act specified in this section, plus three times the amount of damages that a governmental entity sustains, along with expenses, costs, and attorney fees, if the person:
>
> (a) knowingly presents or causes to be presented a false or fraudulent claim for payment or approval . . . .

(b) knowingly makes, uses, or causes to be made or used a false record or statement material to a false or fraudulent claim . . . .

156. Section 17-8-402 defines a claim as including:

> any request or demand for money, property, or services, whether made pursuant to a contract and regardless of whether a governmental entity holds title to the money or property, that is made to:
>
> (a) an employee, officer, agent, or other representative of a governmental entity; or
>
> (b) a contractor, grantee, or other person, whether under contract or not, if any portion of the money, property, or services requested or demanded is to be spent or used on a governmental entity's behalf or to advance a governmental program or interest and if the governmental entity:
>
> (i) provides or has provided any portion of the money, property, or services requested or demanded; or
>
> (ii) will reimburse a contractor, grantee, or other person for any portion of the money, property, or services requested or demanded.

157. Purdue's practices, as described in this Complaint, violated Mont. Code § 17-8-403(1)(a). Purdue, through its deceptive marketing of opioids for chronic pain, knowingly and intentionally caused Montana prescribers to write prescriptions for Purdue's opioid products that were not medically necessary or otherwise ineligible for coverage, and which therefore were ineligible for reimbursement under the criteria of the Montana Medicaid and the State Healthcare Plan programs. Purdue knew that its actions would cause such ineligible prescriptions to be presented to the State for reimbursement, which constituted false or fraudulent claims for payment by the State of Montana.

158. Purdue's practices, as described in this Complaint, violated Mont. Code § 17-8-403(1)(b). Purdue, through its deceptive marketing of opioids for chronic pain, knowingly made and used false records and statements material to the false or fraudulent claims that doctors,

pharmacies, and other health care providers submitted to the State Medicaid and health plan programs to pay for opioid prescriptions, including prescriptions for Purdue opioids.

159. Purdue knew that the doctors, pharmacists, and other health care providers to whom they deceptively marketed prescription opioids had treated and would continue to treat Montana medical assistance patients as well as Montana health plan beneficiaries.

160. Purdue knew, deliberately ignored, or recklessly disregarded, at the time of making or disseminating these statements, or causing these statements to be made or disseminated, that such statements were untrue, false, or misleading and were made for the purpose of getting the State's medical assistance program and health plan to pay for opioids for long-term treatment of chronic pain. In addition, Purdue knew, deliberately ignored, or recklessly disregarded, that its marketing and promotional efforts created an untrue, false, and misleading impression about the risks, benefits, and superiority of opioids for chronic pain.

161. Purdue knew that its false statements were material to healthcare providers' decisions to prescribe opioids to patients included in Montana's medical assistance program and health plan. Indeed, Purdue intended such statements to be material to encourage additional opioid prescriptions.

162. Purdue's scheme caused doctors to write prescriptions for opioids to treat chronic pain that were presented to the State's medical assistance program and health plan for payment. The State's medical assistance program and health plan only cover the cost of a prescription under defined circumstances. Doctors, nurses, pharmacists, and other health care providers expressly or impliedly certified to the State that the opioid prescriptions at issue qualified for reimbursement under the programs' specific criteria. These claims often were false, because

they were influenced by the false and misleading statements disseminated by Purdue about the risks, benefits, and superiority of opioids for chronic pain.

163. Purdue knew, deliberately ignored, or recklessly disregarded that, as a natural consequence of its actions, the State would necessarily be paying for long-term prescriptions of opioids for the first-line treatment of chronic pain, which were dispensed as a consequence of Purdue's actions.

164. Purdue's misrepresentations and omissions were material to the false claims because many Montana prescribers were influenced to write prescriptions for opioids that would not have otherwise, as evidenced by Purdue's own marketing studies demonstrating that increased marketing to prescribers yields increased prescriptions.

165. If the State had known of the false statements disseminated by Purdue and their third-party allies that doctors, pharmacists, and other health care providers were certifying and/or determining that opioids were medically necessary, the State would have undertaken efforts to avoid its payment of such false claims. But for Purdue's false statements and deceptive marketing scheme, the false claims at issue would not have been submitted for payment and would not have been paid by the State's medical assistance program or health plan.

166. By virtue of the above-described acts, Purdue knowingly caused to be presented false or fraudulent claims for payment or approval.

167. Because Purdue's unbranded marketing caused doctors to prescribe and the State to pay for long-term opioid treatment using opioids manufactured or distributed by other drug makers, Purdue caused and are responsible for those costs and claims as well.

168. Pursuant to Mont. Code § 17-8-403(1), Purdue is liable for three times the amount of damages sustained by the State for each violation of the False Claims Act. In addition, Purdue's statutory violations warrant the maximum amount of civil penalties allowed by law.

COUNT THREE

PUBLIC NUISANCE

169. The State incorporates the preceding paragraphs as if fully set forth herein.

170. By statute, "[a] public nuisance is one which affects, at the same time, an entire community or neighborhood or any considerable number of persons, although the extent of the annoyance or damage inflicted upon individuals may be unequal." Mont. Code Ann. § 27-30-102. By common law, a public nuisance is a significant interference with the public health, the public safety, the public peace, the public comfort or the public convenience that unreasonably interferes with a public right.

171. Purdue's conduct, as described in the Complaint, affects, at the same time, the entire State of Montana, and a considerable number of persons therein, and therefore constitutes a public nuisance under Mont. Code Ann. § 27-30-10 and under common law. Furthermore, it involves a significant interference with the public health, the public safety, the public peace, the public comfort or the public convenience, and unreasonably interferes with a public right, and therefore constitutes a public nuisance under common law.

172. Purdue knew and should have known that its promotion of opioids was false and misleading and that its deceptive marketing scheme and other unlawful and unfair actions would create or assist in the creation of a public nuisance.

173. Purdue has created or assisted in the creation of a condition that is injurious to public health, public safety, public peace, public comfort and public convenience, and offends

the moral standards of communities throughout the State and significantly harmed any considerable number of the State's residents.

174. The public nuisance is substantial and unreasonable. Purdue's actions caused and continue to cause the public health epidemic described in the Complaint, and that harm outweighs any offsetting benefit.

175. Purdue's actions were a substantial factor in opioids becoming widely available and widely used, in deceiving prescribers and patients about the risks and benefits of opioids for the treatment of chronic pain, and in the opioid crisis that followed.

176. The public nuisance—i.e., the opioid epidemic—created, perpetuated, and maintained by Purdue can be abated and further recurrence of such harm and inconvenience can be abated.

177. The State has been, and continue to be, injured by Purdue's actions in creating a public nuisance, and seeks herein to enforce a public right.

COUNT FOUR

UNJUST ENRICHMENT

178. The State incorporates the preceding paragraphs as if fully set forth herein.

179. Purdue has unjustly retained a benefit to the State's detriment, and Purdue's retention of that benefit violates the fundamental principles of justice, equity, and good conscience.

180. As alleged herein, the State has used public funds to reimburse opioid prescriptions covered by the State's employee health plan and Medicaid Program. Due to Purdue's deceptive and illegal conduct in promoting opioids to treat chronic pain, the State reimbursed prescriptions for opioids for chronic pain that otherwise would not have been written

or reimbursed. Further, the State has suffered, and continues to cope with, a crisis of opioid addiction, overdose, injury, and death that Purdue helped create.

181. Purdue has reaped revenues and profits from the State's payments, enriching itself at the State's expense. This enrichment was without justification, and the State lacks an adequate remedy provided by law.

182. Accordingly, under principles of equity, Purdue should be disgorged of money retained by reason of their deceptive and illegal acts that in equity and good conscience belong to the State and its citizens.

COUNT FIVE

PUNITIVE DAMAGES

183. The State incorporates the preceding paragraphs as if fully set forth herein.

184. Purdue's conduct as alleged herein proves they were guilty of actual malice as evidenced by their knowledge of the hazards of prescribing opioid medication for the first-line treatment of chronic pain without adequate disclosure of the risks of addiction and overdose, and their intentional disregard and indifference to the fact that such hazards created a high probability of injury to the State. Purdue deliberately proceeded to act in conscious or intentional disregard of the high probability of injury.

185. Defendants' conduct as alleged herein proves they were guilty of actual fraud by making representations about the safety and efficacy of opioids with knowledge of their falsity or concealing material facts with the purpose of depriving the State of its property or legal rights and otherwise causing injury.

186. The State suffered injury as a result of Purdue's misconduct.

187. Because of Purdue's actual malice and actual fraud, the State is entitled, pursuant to Mont. Code Ann. § 27-1-221, to an award of reasonable punitive damages.

XIV. PRAYER FOR RELIEF

WHEREFORE, the State prays for judgment against each Defendant, as permitted by Montana law, as follows:

188. For a declaration that Purdue has violated the Montana Unfair Trade Practices and Consumer Protection Act and the Montana False Claims Act;

189. For injunctions pursuant to Mont. Code Ann. § 30-14-111 enjoining Purdue from engaging in any acts that violate the Montana Unfair Trade Practices and Consumer Protection Act, including, but not limited to, the unfair and deceptive acts and practices alleged in this Complaint;

190. For restoration of money Purdue obtained from the State, as well as other equitable relief, under Mont. Code Ann. § 30-14-131;

191. For civil penalties in the amount of $10,000 for each and every violation of the Montana Unfair Trade Practices and Consumer Protection Act under Mont. Code Ann. § 30-14-142(2);

192. For an additional civil penalty in the amount of $10,000 for each and every violation of the Montana Unfair Practices and Consumer Protection Act perpetrated against an older person under Mont. Code Ann. § 30-14-144.

193. For an award of treble damages under the Montana False Claims Act, Mont. Code Ann. § 17-8-403(1), with joint and several liability under Mont. Code Ann. § 17-8-403(4);

194. For civil penalties in the amount of $11,000 for each and every violation of the Montana False Claims Act under Mont. Code Ann. § 17-8-403(1), with joint and several liability under Mont. Code Ann. § 17-8-403(4);

195. For an injunction permanently enjoining Purdue from engaging the acts and practices that caused the public nuisance;

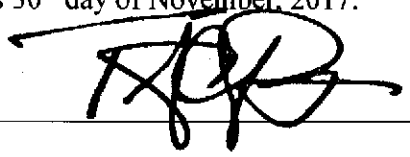
196. For an order directing Purdue to abate and pay damages to the State under Mont. Code Ann. § 27-30-103 for the public nuisance it caused;

197. For restitution and/or disgorgement of Purdue's unjust enrichment and ill-gotten gains, plus interest, acquired as a result of the unlawful or wrongful conduct alleged herein;

198. For expenses, costs, attorneys' fees, and interest thereon; and

199. For all other relief deemed just and proper by the Court.

Respectfully SUBMITTED AND DATED this 30th day of November, 2017.



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DEMAND FOR JURY TRIAL

Plaintiff hereby demands a trial by jury in the above case on all issues so triable.

DALE SCHOWENGERDT
Solicitor General